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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,293	03/26/2004	Andy H. Levine	2814.2008-001	8260

21005 7590 04/18/2007  
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

EXAMINER
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MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/811,293

Applicant(s)

LEVINE ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 21-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/26/04, 12/23/04, 2/9/06, 3/31/06, 4/27/06, 6/1/06.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 101*

Claims 1 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim positively recites the stomach (a portion of the body) as a part of the implant. Portions of the body are considered non-statutory subject matter. It is suggested to change "an anchor fixedly coupled to the stomach" to recite, --an anchor adapted to couple to the stomach--, or something along these lines.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the restrictive screen" in lines 5 and 6. There is insufficient antecedent basis for this limitation in the claim. Claims 2-20 depend upon claim 1 and inherit all problems associated with the claim.

Claim 15 recites the limitation "the staple-retaining device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 is also rendered indefinite since the "staple retaining device comprising a retaining ring" is not part of the gastrointestinal implant, but instead part of the implantation tool. The combination therefore is being claimed, however is not under the scope of the preamble which calls for a gastrointestinal implant only.

Claim 19 recites the limitations "the anchoring ring" and "the restrictive screen" in lines 1 and 2 respectively. There is insufficient antecedent basis for these limitations in the claim.

Claim 20 recites the limitation "the anchoring ring" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-10, 12, 13, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Stack et al. (US 7,152,607 B2). Stack discloses an implant (see figure 12, 14 and respective portions of the specification) comprising a restrictive member (pouch 66) and an anchor (ring 64) removably coupled to the restrictive member (col.2, lines 15-17), wherein the restrictive member (66) comprises a membrane (see fig.12) having an aperture (flow aperture). Stack discloses the restrictive member to be flexible but non-elastic, being permeable with a non-permeable coating (flexible, compliant and non-compliant materials; col.3, lines 56-65; col.4, lines 7-12, 21-25). Stack discloses the restrictive member having a feature to couple to the anchor (col.7, lines 18-20). Stack discloses the anchor to include clips (plicated; col.7, lines 14-18; fig.12). Stack discloses the anchor (64) to be shape memory material (nitinol; col.7, lines 14-15). Stack discloses the ring (64) to have a hook configured to couple to the restrictive member (clips; col.7, lines 18-20).

Claims 1, 2, 5, 6, 10-14, 16, 19, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Kagan et al. (US 2005/0240279 A1). Kagan discloses an implant (fig.2a, 2b) comprising a restrictive member/means (stoma 100) and an anchor/anchor means (separate anchoring structure 108 seen in fig.2a) removably coupled to the restrictive member (P0139), wherein the restrictive member (100) comprises a membrane having an aperture (110, 152). Kagan discloses the restrictive member to be flexible but non-elastic and non-permeable (P0138, P0141, P0143). Kagan discloses the restrictive member having a loop feature (112; see figs.5, 7-9) to couple to the anchor. Kagan discloses the anchor to include clips (clips, P0139) and retaining devices for the clips (attachments sites, P0139).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. (US 7,152,607 B2). Stack discloses a restrictive member (66; see fig.12) having a perimeter and aperture for the restriction of passage of food through the stomach. Stack discloses the restrictive member having different shapes, thus sized openings (col.4, lines 50-63, but is silent to mention any specific sizes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed size aperture, since the location and purpose of Stacks is the same as applicants and since such a modification would have involved a

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mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

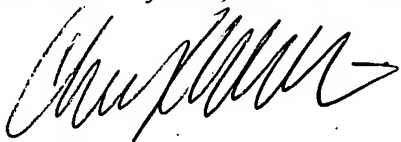
***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



**BRUCE SNOW**  
**PRIMARY EXAMINER**